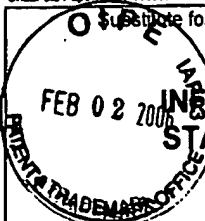




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 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known		
		Application Number	10/663,265	
		Filing Date	September 16, 2003	
		First Named Inventor	Edith Mathiowitz	
		Group Art Unit	1633	
		Examiner Name	Maria Gomez Leavitt	
Attorney Docket Number	BU MAT1993-04DIV3CON2			
Sheet	1	of	6	

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Number	Kind Code ² (if known)				
ML		4,272,398		Jaffe	06-09-1981		
↓		4,775,624		Bang, et al.	10-04-1988		
		4,861,627		Mathiowitz, et al.	08-29-1989		
		4,863,735		Kohn, et al.	09-05-1989		
		4,897,355		Eppstein, et al.	01-30-1990		
		4,898,734		Mathiowitz, et al.	02-06-1990		
		5,100,669		Hyon, et al.	03-31-1992		
		5,100,792		Sanford, et al.	03-31-1992		
		5,171,217		March, et al.	12-15-1992		
		5,271,961		Mathiowitz, et al.	12-21-1992		
		5,366,881		Singh, et al.	11-22-1994		
		5,639,473		Grinstaff, et al.	06-17-1997		
		5,643,578		Robinson, et al.	07-01-1997		
		5,674,192		Sahatjian, et al.	10-07-1997		
	↓		5,763,416		Banadio, et al.	06-09-1998	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ^d
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
ML ↓ ↓		EP	0 248 531		Southern Research Institute	12-09-1987		
		EP	0 330 180		Biomaterials Universe, Inc.	08-30-1989		
		EP	0 302 582		Southern Research Institute	02-08-1989		
		EP	5 79347		Ferring Arzneimittel, GMBH	01-19-1994		
		PCT	WO 93/0885		Massachusetts Institute of Technology	05-123-1993		

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		Group Art Unit	1633
		Examiner Name	Maria Gomez Leavitt
Sheet 2 of 6	Attorney Docket Number	BU MAT1993-04fDIV3CON2	

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		Number	Kind Code ² (if known)			
ML		5,783,567		Hedley, et al.	07-21-1998	
↓		5,792,751		Ledley, et al.	08-11-1998	
↓		5,820,883		Tice, et al.	10-13-1998	
↓		5,880,103		Urban, et al.	03-09-1999	
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		Office. ²	Number ⁴	Kind Code ⁵ (if known)				
ML		PCT	WO 93/21906		Brown University Research Foundation	11-11-1993		
↓		PCT	WO 93/25221		Alkermes Controlled Therapeutics	12-23-1993		
↓		PCT	WO 94/23699		Medisorb Technologies International LP	10-27-1994		
↓		PCT	WO 94/23738		Medisorb Technologies International LP	10-27-1994		

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OTHER ART – NON PATENT LITERATURE DOCUMENTS			
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ML		ACSADI, et al., "Human dystrophin expression in mdx mice after intramuscular injection of DNA constructs", <i>Nature</i> , 352(6338):815-8 (1991).	
		BENITA, et al., "Characterization of drug-loaded poly(d,l-lactide) microspheres", <i>J Pharm Sci.</i> , 73(12):1721-4 (1984).	
		BLAU, "Muscular dystrophy. Muscling in on gene therapy", <i>Nature</i> , 364(6439):673-5 (1993).	
		CHANGBEN and SHOUYUAN, "Use of human erythrocyte ghosts for transfer of 125I-BSA and 125I-DNA into animal cells through cell fusion", <i>Scientia Sinica</i> , XXV(8):860-865 (1982).	
		COGHLAN, et al., "Gene dream fades away" <i>New Sci.</i> , 148(2005):14-5 (1995).	
		COHEN, "Naked DNA points way to vaccines", <i>Science</i> , 259(5102):1691-2 (1993).	
		CLARK, "Overview and general considerations of wound repair", in <u>The Molecular and Cellular Biology of Wound Repair</u> eds. R Clark and P Henson, pp 3-33 1988.	
		CRYSTAL, "Transfer of genes to humans: early lessons and obstacles to success" <i>Science</i> , 270(5235):404-10 (1995).	
		DAGANI, "Gene therapy advance, anti-HIV antibodies work inside cell", <i>Chemical & Engineering News</i> , pp 3-4 (1993).	
		DUNCAN, "Drug-polymer conjugates: potential for improved chemotherapy", <i>Anticancer Drugs</i> , 3(3):175-210 (1992).	
✓		EISENBERG and CROTHERS, (eds) "Physical Chemistry with Application to the Life Sciences", Benjamin/Cummings Publishing CO., Menlo Park, CA, p705, 1979.	

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		Examiner Name	Maria Gomez Leavitt
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ML		EISENBRAUN, et al., "Examination of parameters affecting the elicitation of humoral immune responses by particle bombardment-mediated genetic immunization", <i>DNA Cell Biol.</i> , 12(9):791-7 (1993).	
		FYNAN, et al. "DNA vaccines: protective immunizations by parenteral, mucosal, and gene-gun inoculations" <i>Proc Natl Acad Sci U S A.</i> , 90(24):11478-82 (1993).	
		HAWLEY-NELSON, et al., "Lipofectamine reagent: A new higher efficiency polycationic liposome transfection reagent", <i>Focus</i> , 15:73-8 (1993).	
		HENSYL, et al. (eds) "Stedman's Medical Dictionary", 25 th edition, Williams and Wilkins, Baltimore, MD. P 1473, 1990.	
		JIAO, et al., "Persistence of plasmid DNA and expression in rat brain cells in vivo", <i>Exp Neurol.</i> , 115(3):400-13 (1992).	
		KAY, et al., "In vivo gene therapy of hemophilia B: sustained partial correction in factor IX-deficient dogs", <i>Science</i> , 262(5130):117-9 (1993).	
		LEDLEY, "Nonviral gene therapy: the promise of genes as pharmaceutical products", <i>Hum Gene Ther.</i> , 6(9):1129-44 (1995).	
		LIM, et al., "Microencapsulation of living cells and tissues", <i>J Pharm Sci.</i> , 70(4):351-4 (1981).	
		MARX, "A first step toward gene therapy for hemophilia B?", <i>Science</i> , 262(5130):29-30 (1993).	
		MATHIOWITZ, et al., "Polyanhydride microspheres. IV. Morphology and characterization of systems made by spray drying", <i>J. Appl Polymer Sci.</i> , 45:125-34 (1992).	
✓		MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery systems", <i>Scanning Microsc.</i> , 4(2):329-40 (1990).	

Examiner's Signature	Maria Leavitt	Date Considered	04-07-06
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		Filing Date	September 16, 2003
		First Named Inventor	Edith Mathiowitz
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		Examiner Name	Maria Gomez Leavitt
		Attorney Docket Number	BU MAT1993-04FIV3CON2
Sheet	5	of	6

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ML		MATHIOWITZ, et al., "Polyanhydride microspheres II. Microencapsulation by solvent removal", <i>J. Appl Polymer Sci.</i> , 35:755- (1988).	
		MATHIOWITZ, et al., "Polyanhydride microspheres I. Hot-melt microencapsulation", <i>J. Controlled Release</i> , 5:13-22 (1987).	
		MATHIOWITZ, et al., "Novel Microcapsules for delivery systems", <i>Reactive Polymers</i> , 6:275-83 (1987).	
		MULLIGAN, "The basic science of gene therapy", <i>Science</i> , 260(5110):926-32 (1993).	
		NABEL, et al. "Direct gene transfer with DNA-liposome complexes in melanoma: expression, biologic activity, and lack of toxicity in humans", <i>Proc Natl Acad Sci U S A.</i> , 90(23):11307-11 (1993).	
		NICOLAU, et al., "In vivo expression of rat insulin after intravenous administration of the liposome-entrapped gene for rat insulin I", <i>Proc Natl Acad Sci U S A.</i> , 80(4):1068-72 (1983).	
		PARTRIDGE, "Gene therapy. Muscle transfection made easy" <i>Nature</i> , (6338):757-8 (1991).	
		ROSENBERG, et al., "Use of tumor-infiltrating lymphocytes and interleukin-2 in the immunotherapy of patients with metastatic melanoma. A preliminary report", <i>N Engl J Med.</i> , 319(25):1676-80 (1988).	
		SALIB, et al., "Utilization of sodium alginate in drug microencapsulation", <i>Pharmazeutisch Industrie</i> , 40(11A):1230-34 (1978).	
		SAWHNEY, et al., "Bioerodible hydrogels based on photopolymerized poly(ethyleneglycol)-co-poly(α-hydroxy acid) diacrylate macromers", <i>Macromolecules</i> , 26:581-7 (1993).	
✓		TAI, et al., "Microencapsulation of recombinant cells: a new delivery system for gene therapy", <i>FASEB J.</i> , 7(11):1061-9 (1993).	

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ML		ULMER, et al. "Heterologous protection against influenza by injection of DNA encoding a viral protein", <i>Science</i> , 259(5102):1745-9 (1993).	
		VERMA and SOMIA, "Gene therapy -- promises, problems and prospects" <i>Nature</i> , 389(6648):239-42 (1997).	
		WILSON, "Cystic fibrosis. Vehicles for gene therapy" <i>Nature</i> , 365(6448):691-2 (1993).	
		WIVEL, et al., "Germ-line gene modification and disease prevention: some medical and ethical perspectives", <i>Science</i> , 262(5133):533-8 (1993).	
		WOLFF, et al. "Direct gene transfer into mouse muscle in vivo" <i>Science</i> , 247(4949 Pt 1):1465-8 (1990).	
✓		YANG, "Gene transfer into mammalian somatic cells <i>in vivo</i> ", <i>Critical Reviews in Biotechnology</i> , 12(4):335-356 (1992).	

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